Claims 123-164 are pending in the subject application.

Restriction Requirement

In the September 8, 2004, 2004 Office Action, the Examiner required restriction to one of the following allegedly independent and distinct inventions characterized by the following Groups 1-2:

1. Claims 123-144, drawn to a process for obtaining a pharmaceutical product containing an aqueous mixture of polypeptides, each of which consists essentially of alanine, glutamic acid, tyrosine and lysine, classified in Class 436, subclass 543; and

2. Claims 145-164, drawn to a process for determining the average molecular weight of an aqueous mixture of polypeptides, each of which consists essentially of alanine, glutamic acid, tyrosine and lysine, classified in Class 530, subclass 417.

On page 2 of the September 8, 2004 Office Action, the Examiner alleged that the claimed inventions are distinct each from the other and are unrelated. Citing MPEP §§ 806.04 and 808.01, the Examiner alleged that the inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. The Examiner further alleged that the methods of groups 1-2 as claimed are unrelated as they comprise distinct steps, and demonstrate that each method has a different mode of operation. The Examiner concluded therefore, that the claims as grouped are patentably distinct. The Examiner also alleged that

the inventions of Groups 1-2 have a separate status in the art as shown by their different classifications and require separate and distinct searches. The Examiner further alleged that a prior art search also requires a literature search and that it is an undue burden for the examiner to search more than one invention. As such, the Examiner concluded that it would be burdensome to search the inventions of Groups 1-2 together because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. The Examiner also alleged that even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods comprising the distinct method steps. The Examiner further alleged that a prior art search also requires a literature search and that it is an undue burden for the examiner to search more than one invention. The Examiner concluded therefore, that restriction for examination purposes as indicated is proper. The Examiner advised the applicant that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

In response, applicants hereby elect, with traverse, the invention of the claims identified as Group 1, i.e., claims 123-144.

Applicants, however, respectfully request that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. §121, restriction may be required if two or more independent and distinct inventions are claimed in one application.

Applicants point out that M.P.E.P. §806.04 cited by the Examiner fails to support the restriction because claims 123-144 are not independent from claims 145-164. Initially, applicants note that claims 123-164 do not fall into the examples of independent inventions provided in M.P.E.P. §806.04. Furthermore, the processes of claims 145-164 are incorporated into the processes of claims 123-144. Specifically, the process of claim 123 (to obtain a pharmaceutical product containing an aqueous mixture of polypeptides) and the process of claim 134 (to obtain a pharmaceutical composition containing an aqueous mixture of polypeptides) each recites the steps of the process of claim 145 (of measuring the average molecular weight of an aqueous mixture of polypeptides using a gel permeation chromatography column calibrated with a plurality of molecular weight markers). Therefore, claims 123-144 are not independent from claims 145-164 and restriction is not proper.

Furthermore, examination of any of the claims 123-164 will require the examination of a process for determining the average molecular weight of an aqueous mixture of polypeptides, i.e. the process of claims 145. Therefore, examination of claims 145-164 will place no additional burden on the Examiner than the examination of elected claims 123-144. Stated otherwise, if the Examiner finds the process of claim 145 free of prior art, all of the claims must be free of prior art. MPEP §803 unambiguously provides that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions." Since there is no serious burden on the Examiner to examine all of the claims together in the subject application, the restriction is improper.

Finally, the sole reason provided by the Examiner in support of this restriction requirement, i.e. that "the methods of groups 1-2 as claimed are unrelated as they comprise different steps," is not accurate. As noted above, all of the steps of claim 145 are incorporated into claims 123-144. Clearly the claims are related and restriction is improper.

In view of the foregoing, applicants maintain that the September 8, 2004 restriction requirement is not proper under 35 U.S.C. §121, and respectfully request that the Examiner reconsider and withdraw the requirement.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invites the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Gary J. Gershik 10/5/04

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